EXHIBIT I

UNITED STATES DISTRICT COURT
DISTRICT of MINNESOTA

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In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:
All Actions MDL No. 15-2666 (JNE/FLM)

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DEPOSITION of THEODORE R. HOLFORD
VOLUME I, PAGES 1 - 386
JULY 18, 2017

(The following is the deposition of THEODORE R. HOLFORD, taken pursuant to Notice of Taking Deposition, via videotape, at the Marriott Hartford Downtown, 200 Columbus Boulevard, Hartford, Connecticut, commencing at approximately 9:20 o'clock a.m., July 18, 2017.)

APPEARANCES:
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I N D E X

PROCEEDINGS

(Witness sworn.)

THEODORE R. HOLFORD

called as a witness, being first duly sworn, was examined and testified as follows:

ADVERSE EXAMINATION

BY MR. SACCHET:

Q. Good afternoon, Professor Holford. My name is Michael Sacchet and I represent the plaintiffs in this litigation.

Could you please state your full name for the record.

A. Theodore Richard Holford.

Q. And Professor Holford, have you had your deposition taken before?

A. Not on this.

Q. In the past?

A. Yes, I have.

Q. What was the subject matter of that deposition?

A. Cigarette smoking.

Q. How long ago?

A. Ooh. It was probably eight years ago, something like that, eight, 10 years ago.

Q. And were you called to offer opinion as to

biostatistics?

A. Yes.

Q. Epidemiology?

A. It was in regard to a statistical review that I did of an epidemiology calculation paper -- or chapter of a book, actually.

Q. What was the chapter of that book?

A. It was a chapter dealing with lung cancer trends, and they were relating it to smoking.

Q. Okay. And were the studies that you relied on in that chapter of the book observational studies?

A. Yes.

Q. What --

How many studies were there?

A. I don't recall. It was a -- quite a long -- quite a long time ago. I think some of it was population data as I recall, but it's been -- been quite a long time; I've forgotten the details of it.

Q. And who retained you to provide expert testimony in that litigation?

A. It was the tobacco companies. They -- they -- I was -- I -- they de -- deposed me. They subpoenaed me and wanted me to be a witness.

MR. GORDON: I -- I think he's not understanding -- he's not tracking what you mean by

A. Is that --

Is the Supreme Court talking about a matter of -- matter of law, or you were -- you were stating it as -- as scientific -- as a scientific -- statement of scientific fact?

Q. Quote, "A lack of statistically significant data does not mean that a medical expert has no reliable basis for inferring a causal link between a product and an adverse event," end quote.

A. The lack of -- I -- I --

I don't know.

MR. GORDON: I'll object to the form of the question.

A. Yeah. I don't really understand what -- what they're -- what they're getting at. I would have to --

Q. Would it help to see the statement?

A. I'd have to review the statement. I mean how --

What is it, a whole report?

Q. It's a case, and we don't have time for you to read the whole case, but --

A. I mean that's --

I'd have to figure out what the case is talking about. It -- it's --

I'm not a lawyer, obviously, and so I'm -- I'm not sure what distinctions that they're -- that they're making. Their language is sometimes a little different.

MR. SACCHET: Okay. Let's take a break.

THE REPORTER: Off the record, please.

(Recess taken.)

BY MR. SACCHET:

Q. Professor Holford, in your report you also note that applying Fisher's exact test on the data derived from Albrecht Exhibit 10 and McGovern Exhibit 16 yields a confidence interval of .97 to 10.82; correct?

A. Yes.

Q. And essentially that .97 is just .03 away from the null value of one; correct?

A. That's right.

Q. So it's subject to this same debate about just over/just under.

A. It's just -- it's just under the critical value.

Q. Yes.

A. I mean it corresponds --

It's a little less because the p-value is a little high.

Q. And you conclude that one of the issues with that confidence interval is it's essentially 10 points and therefore there's -- there could be unreliability to the data; correct?

A. Well the estimate of the -- of the odds ratio is -- is not precise at all. I mean it's a ten-fold difference, ten-fold range.

Q. So I was confused because when I read your report and I saw your real analysis of the Jensen data --

Which you did applying Albrecht Exhibit 10; correct?

A. Yes.

Q. -- the confidence interval of your calculation is 25 points wide.

A. I forget what the range was. It was pretty wide.

Where was it?

Q. It's on page five.

A. Page five. So you're referring to the 1.37 to 25.49.

Q. Yeah.

A. Yeah. Yeah. It's not a very good estimate.

Q. It's double the size of the confidence interval that you critique with respect to the

McGovern study; correct?

A. That's right. It's statistically significant, but the -- but the -- but it's not a good estimate of what the risk is.

Q. So it has double the variance as the confidence interval in the McGovern study.

A. Well it's -- it seems to be double the -- the range, the -- the -- the length of the -- of the confidence interval.

Q. But you rely on this calculation with respect to arguing whether or not the thromboprophylaxis that was used in the McGovern study is in fact a confounding factor; correct?

A. Well I'm --

I was looking at the p-value. The p-value that I get associated with that is .006 --

Q. Uh-huh.

A. -- 4, so it's quite a small p-value. The estimate of what that effect is is quite imprecise because of -- you know, because of the range that we were just talking about.

Q. It's more imprecise than the McGovern study's confidence interval that you critique.

A. Well it's more imprecise in --

In general what happens with the -- with

the -- with the confidence interval is it kind of depends on the logarithm, so it's more on the log scale, so that's part of what happens. I mean this odds ratio is 4.77, so it's quite a bit bigger than the odds ratios we were finding associated with Bair Hugger use. So that's -- that's of course just a point estimate, and so we're talking about a higher range, so the range is going to be -- going to tend to be somewhat wider because -- because we're up there. And of course the -- the total sample size, total number of individuals involved is -- is quite a bit smaller than -- than -- because it -- it's just based --

It comes out to be a subset of the -- of the Bair Hugger study because it's only the Bair Hugger period, so it's reduced in that way, and then the other thing is that it's not the entire period, it's just part of it, so we -- you're splitting that data set up. And so your total sample size has gone down, and that increases the -- that decreases the sample size and in general makes the estimates less precise.

Q. But there's no doubt that the confidence interval in this Jensen reanalysis, which is in your report on page five, is double the width of the McGovern confidence interval; correct?

A. That seems to be what it is, yes.

Q. That is what it is.

A. Okay. Yeah.

Q. Your report also states that when applying Albrecht Exhibit 10 and McGovern Exhibit 16, that the p-value -- or that the odds ratio is 2.76 when using Fisher's exact; correct?

A. Well that -- that -- yeah. And that -- that's not --

The -- the test, the Fisher's exact, has to do with the p-value, not the -- not the estimate of what the odds ratio is.

Q. So on page two of your report when you say the odds ratio for this comparison is 2.76, where did you get that from?

A. That's just a cross-product ratio for that table.

Q. And is that -- okay.

So the 2.76 derives from Albrecht Exhibit 10 and McGovern Exhibit 16.

A. That's right. It's a tabulation of those data. I mean it's --

Yeah.

Q. And it's only accurate insofar as those exhibits are accurate; correct?

A. Well the accuracy depends on -- on the -- on the --

Q. Cross product.

A. Well the point estimate is the cross product. The -- the confidence interval depends on this Fisher-like distribution. It's not --

It's an exact kind of calculation that -- that -- that's involved, but it's kind of a lengthy calculation that roughly depends on the standard error.

Q. So I might need to back up because I don't know if I'm fully understanding what you're saying. But the odds ratio reported in the McGovern study was 3.8; correct?

A. Yes.

Q. And then in your report on page two you say the odds ratio for this comparison is 2.76, and what --

A. That's in the tabulation I used, yes.

Q. -- what data are you using to derive that odds ratio?

A. The --

MR. GORDON: Arithmetically, or the underlying data?

MR. SACCHET: Arithmetically.

A. Well it's the -- it's the -- two point --

Where is that? Oh, here we are. Okay. Yeah. That's based on this -- this table that is the four out of 372 and 31 out of 1065.

Q. And where did you get that data?

A. That's from -- from --

Was it Albrecht 10?

Q. Okay. You would agree that that odds ratio is still above 2.0; correct?

A. Yes.

Q. Would you agree that an odds ratio of 2.0 is often referred to as a doubling of the risk?

A. It -- it is, yeah.

Q. And -- and that means you're 50 percent more likely to experience the outcome after exposure to the variable than the count as actual?

MR. GORDON: Object to the form of the question.

A. Well if -- what it would imply, if -- if -- if the odds ratio was -- if the --

The odds ratio is actually a ratio of odds. The statement that you made as -- is re -- is related -- you state it as a ratio of -- of risks, which would typically mean a ratio of the -- of the incidence rates.

A. That's -- that's -- that's what he reported.
Q. Are you aware that Dr. Reed also testified that to rely on data prior to July 1st, 2008 would be, quote, very unreliable, end quote?
A. That's what he reported.
I mean related to this, I mean there's a -- there was a review of -- of the procedures that they were using that's referred to in one of the other papers --
What is the author? Starts with a G. Gissell?
Q. Gillson.
A. Gillson. Thank you.
-- that this was all not reviewed until December, so I'm not sure where -- what Reed is referring to.
Q. So you don't believe Dr. Reed's testimony that full surveillance began on Septem -- on July 1st, 2008.
A. Well he's -- he's depending on his recollection, --
Q. Okay.
A. -- I assume, in his deposition.
Q. Uh-huh.
A. And I mean that's what he's -- what -- what

he said in his -- in his deposition; however, that seems to not correspond in a peer-reviewed paper what was said about when this was all reviewed.
Q. So is your statement that in the Gillson article the authors there represented that the full surveillance began in December of 2008?
A. It was reviewed in December.
Q. Reviewed in December. But you have no knowledge --
A. I don't --
Q. -- as to whether --
A. It doesn't say when it was implemented, --
Q. Okay.
A. -- but that would imply, if it was not reviewed until December, that it would have been not implemented until maybe January. Right? I mean if it's not --
Q. January '09?
A. '09. Yeah.
Q. Okay. So if full surveillance wasn't implemented until January '09, --
A. Yes.
Q. -- you're relying on data from July -- prior to July 2008.
A. These were the data that were -- were

provided. These were the data that I had available to me.
Q. But --
So I just want to be clear. Based on what you just said, it's either possible that full surveillance began on July 1st, 2008 or --
A. Yes.
Q. -- perhaps even January 1st, 2009, --
A. So what --
Yeah.
Q. -- but you nonetheless constructed your model on data that was prior to that time; correct?
A. That's -- that's right.
Q. And that data --
A. And --
Q. -- may or may not be complete.
A. And --
Q. Answer the question, please.
A. Well according to Reed's testimony, if Reed's correct, if -- if -- if this is correct, that might be true.
Q. Okay.
A. The other thing that's true, then, if that's what in fact took place, is that six months -- or whatever it is -- six months or so of McGovern is not

reporting appropriately.
Q. So if this document from the NHS says that since July 2008 hospitals are required to have sys -- systems in place to identify patients who are included in the surveillance and later admitted to hospitals with an SSI, would that clarify any doubt as to when full surveillance began in the NHS?
MR. GORDON: Object to the form of the question, lack of foundation.
A. Well there is --
I mean you're -- you're raising questions about how accurate the data were recorded, but I mean all of these change -- changes took place during the McGovern study.
Q. If Mr. Reed's testimony is true -- if Dr. Reed's testimony is true --
MR. SACCHET: I just said "mister," but I --
(Discussion off the stenographic record.)
Q. Okay. If Mr. Reed's testimony is that full surveillance began on July 1st, 2008, that is the start of the Bair Hugger period in the McGovern study; correct?
A. That's --
According to his deposition, that -- that's

what it corresponds to, yes.
Q. And you have no evidence to doubt that, do you, Professor Holford?
MR. GORDON: Object to the form of the question.
A. I mean the evidence to doubt it is that seems to be somewhat contradictory to what Gillson says, but I mean I -- I'm not going to -- you know, I don't -- I'm -- I'm --
I'll -- I'll take -- I'll take him at his word.
Q. Okay. And taking him at his word, full surveillance starts on July 1st, 2008.
A. That's what he said.
Q. Yes.
(Exhibit 24 was marked for identification.)
BY MR. SACCHET:
Q. Professor Holford, is this the Gillson article that you are referring to that was cited in your report?
A. Is this it? I don't think it is.
Q. Okay. Let me --
A. I -- let's see.
MR. SACCHET: I may have marked the wrong

document, professor. Is it -- I just --
I'll shortcut this because I think I might have. Is the first line of the document you're looking at actually from Brister, not Gillson?
MR. GORDON: Yeah.
MR. SACCHET: I may have given you the wrong one.
MR. GORDON: That's what you want to give him.
MR. SACCHET: Okay.
THE WITNESS: Yeah. I think this is one of the ones that --
MR. SACCHET: Yeah. That's my fault.
THE WITNESS: Yeah. It's strange, because the author is not -- doesn't appear on it, which is kind of a --
MR. SACCHET: The author is there on the top, it's just --
It's my fault.
THE WITNESS: Okay. Yeah. It was hard to find the author on this one, that's what -- yeah. Anyway --
MR. GORDON: This is al --
This Exhibit 24 is on his list of references, it's just --

MR. SACCHET: Yeah, it's the Brister article.
THE WITNESS: Yeah, okay. Yeah. I didn't think this was Gillson, that's all. See, Gillson is -- where are we -- same journal, 2014, June '17. Is that true? That was --
Oh, no. It was published in 21 -- 2011. Yeah, that's Brister.
MR. SACCHET: Yeah.
THE WITNESS: Yeah.
(Exhibit 25 was marked for identification.)
BY MR. SACCHET:
Q. Is this the Gillson article that you were referring to?
A. Yes, it is.
Q. Okay.
A. Yes.
Q. Can you point me to any particular statement in this article where there's information that contradicts Mr. Reed's testimony?
A. Oh. There's a figure somewhere in there, which is practically illegible in this copy --
Q. I don't want to spend tons of time on this, professor, but --

A. I've got a --
Q. -- one thing that might be helpful is you would agree, wouldn't you, that this particular document relates to Northumbria Healthcare; correct?
A. That includes Wansbeck, yeah.
Q. But it's not specific to Wansbeck; correct?
A. That -- that's correct.
Q. So even if, for the sake of argument, this document said something to the effect that there was a different time in which full surveillance occurred, that may or may not be specific to Wansbeck.
A. Well I assume it would include Wansbeck. I -- I don't know how they operate, but -- yeah.
Q. It's possible that Wansbeck may have been ahead of the curve with respect to what NHS did as a trust; correct?
A. I -- I guess that's possible.
Q. Okay. So even if there's a date in this document that's specific to NHS, it does not contradict Mr. Reed's testimony.
A. Not necessarily.
MR. GORDON: Object to the form of the question, --
A. Well --
MR. GORDON: -- assumes facts not in

Q. Are you aware that the record studies found that Xarelto is not related to infection?

MR. GORDON: Objection, asked and answered, lack of foundation.

A. I think I said I had not looked at the record studies.

Q. Would it be helpful to look at one?

A. I mean I -- it --

When I was looking within the Albright 10 data set, I found the association that I reported. Now I think the premise of your question is: Is the association that I found, is that a causal association or not? The way this study was designed, is this temporal? You know, these time periods are changing. And as I show in Fig. 2 --

Q. Okay.

A. -- show in Fig. 2 and I present the -- related to that I show in figure -- I'm sorry, on page -- ah, where is that? On page four, the last paragraph, it compares the infection rates by quarter --

Q. Yeah.

A. -- and we got a chi-square of 15.5 on six degrees of freedom, p-value of .0167. So what that suggests is that the incidence rates during the Bair

Hugger period were changing quite a lot, and those differences were statistically significant.

Q. Okay.

A. So this is not a period where things were just under well controlled.

Q. Are you aware of whether deep joint infections are always constant or whether there is variability in deep joint infections more generally?

A. Well if there is variability more generally, then that needs to be taken into account in the analysis, and this analysis does not do that.

Q. When you conducted --

A. I did not do that, and McGovern certainly didn't do it either.

Q. When you construct a statistical model, the confidence interval accounts for the variance of the data; correct?

A. Well it should. But the confidence intervals that I computed and the confidence intervals that McGovern computed don't take that -- that variability into account.

Q. Okay.

A. The expected value of this chi-square statistic is equal to the degrees of freedom, so you expect it to be six, in fact it's 15.5, so there's,

what, two and a half times as much variability as what I would expect to see if the only variation that was taking place was just a random fluctuation based on, you know, what's going on with the use of -- of -- of these surgical procedures at Wansbeck.

Q. You didn't do that calculation with respect to the reanalysis of the Jensen data; correct?

A. I -- I didn't -- I didn't allow for random variability other than the binomial variability --

Q. Okay.

A. -- that -- that we assumed. No, I -- I took that at a face value. And -- and it could be random. My assumption is it's not random. My assumption is it's due to other factors that are -- that were affecting risk at Wansbeck during this time period.

Q. That's an assumption.

A. It is.

Q. Okay. I want to go back to the -- what we were talking about with respect --

Did you do any investigation to determine whether your assumption was correct or not?

A. I -- I have no further --

I have not been in contact with Wansbeck or anyone else involved with this to know that for certain. I guess a part of my -- my -- my reasons for

thinking there were other things going on is the Gillson paper, for example, enumerates such a huge array of things that were taking place at -- what is it -- Northumbria group of hospitals, --

Q. Okay.

A. -- so they were having a problem. Obviously, NHS was -- was calling them on having a high infection rate that they needed to do something about, and the -- the Gissell paper elaborates on all the things that they were trying to do to bring this thing under control, and there were a lot of other things other than switching to Hot Dog.

Q. Okay. Did you ask 3M for any info with respect to this issue?

A. No.

MR. GORDON: Object to the form of the question.

Q. Okay. Are you aware that in the Gillson article the descriptor for infection is SSI?

MR. GORDON: Object to the form of the question.

Q. The title of the article is SSI.

A. Which paper are you talking about?

Q. You just referenced the Gillson article, --

A. Gillson, okay.

Q. -- "Implementing Effective SSI Measures."
A. Right. Yes.
Q. Do you know what "SSI" stands for?
A. Ahh, oh --
I've forgotten.
Q. Surgical-site infection ring a bell?
A. Surgical-site infection. Exactly, yeah.
Q. Surgical-site infections are not the same thing as deep joint infections.
MR. GORDON: Object to the form of the question, lack of foundation, misconstrues the evidence and assumes facts not in evidence.
Q. Do you know whether an SSI is the same as a DJI?
MR. GORDON: Same objection.
A. It's -- it's not the same, it's not the same thing. They are -- they would be --
Are you saying -- suggesting they are not related?
Q. I'm suggesting that --
Do you know whether the measures that were implemented in the Northumbria trust were specific to SSI or DJI?
A. I think --
Well the paper is entitled for SSI.

Q. So you don't know whether they were specific to deep joint infection.
A. Well I would assume that they would -- they would be effective on affecting both. I mean orthopedic surgery appears to be one of the things that they are in fact looking at.
Q. Can you define SSI?
A. I don't know the --
I don't know. I'm -- it's not a -- an area that I've particularly done -- done work -- work on. I --
Q. Can you define DJI?
A. It's -- it's again the --
It's joint -- joint infections --
Q. Okay.
A. -- that -- that you're looking at.
Q. But you have no scientific basis or expertise to conclude whether or not the inter -- interventions that are mentioned in the Gillson article which relate to SSI would have an impact on deep joint infection; correct?
A. It's --
They're not areas that I have -- that I have -- that I have personally done research on. My -- my --

But I -- I believe that they would be related to each other. And things that you're doing to control SSI, my understanding is you would have -- you would have effects on -- on PJI as well.
Q. What's your understanding based on?
A. Well looking at -- well I mean the -- one --
This is from the -- from the Gillson paper.
Q. What is?
A. A patient with a -- with a -- with surgery on his knee.
Q. Do you see the implant?
A. I see the surgery on his knee.
Q. Do you know whether that would result in either a superficial wound infection on the skin or whether it would result in a deep infection on a prosthetic?
A. I don't know. If it was a deep infection, I think that would be something they would -- they would be interested in.
You don't think that -- you don't think they would be interested in that as -- as respect to the surgery?
Q. Are you asking me?
A. Yeah.
Q. I'm --

A. I mean you -- you seem to be suggesting that there's no effect. Why -- why what you're asking me --
Q. I would let --
Your -- your report concludes that the SSI bundle may have had an effect on deep joint infection rates; correct?
A. Yes. The things that they were doing to control SSI may have had an effect.
Q. You have no scientific basis to make that conclusion.
A. I'm -- no, no. I'm just -- just assuming that it does.
Q. Thank you.
Do you know if any articles that you're relying on relate to SSI versus DJI?
A. No.
Q. So you're not sure whether the publications that you've cited on page 14 of your report are specific to deep joint infection or a surgical-site infection.
A. Oh. Some of them --
I'm not sure which articles you're -- you're talking about.
Q. Well do you know offhand? I don't want to

the McGovern study or whether it decreased, correct, --

A. Which odds --

Q. -- when com --

A. -- ratio are you talking about?

Q. Either the 3.8 or the 2.76 that you calculated based on Albrecht 10. You have no basis to compare those odds ratios to this calculation.

A. Well I compared the odds -- I mean I didn't --

I don't report the odds ratio, but you can pretty good -- get a pretty good idea of what -- about what it's going to be --

Q. You told me --

A. -- because the infection rate -- let's see.

"In order to control for the...one must use the Bair Hugger period that -- that shares the antibiotic and thromboprophylaxis regimen used in the Hot Dog period," so -- which had an infection rate of three out of 270, 1.1 percent, and compare that with four out of 372, which is 1.08 percent.

Q. You're looking at controlling for both variables, correct, right now?

A. That is correct.

Q. I want to go back to when you just

controlled for the antibiotic, which is what we're talking about. You did not provide an odds ratio.

A. I did not --

That's right, I didn't provide it.

Q. You did not determine how or whether the antibiotic by itself is a confounding variable.

A. By -- by itself, no. By itself, no.

Q. And you have --

A. But I've controlled for both of them --

Q. We'll get there. I'm just talking about this calculation.

You do not know the degree of confounding, if any, caused by only the antibiotic.

A. That's right. I didn't do that.

Q. And you have not reviewed any literature to suggest that an antibiotic is a confounding factor on deep joint infections.

MR. GORDON: Object to the form of the question.

A. I don't see -- understand that -- understand your -- your question. To be a confounding variable, as we've said, it has to be associated with -- with the -- with the outcome --

Q. Okay.

A. -- and the variable you're looking at.

Q. Yeah. And you haven't done --

A. So whether or not it's associated with --

Well in this study it -- it certainly is associated with -- with whether or not the Bair Hugger or the Hot Dog was used. In general, who knows?

Q. You don't know whether --

A. Well --

Q. -- the Gentamic --

A. -- it depends on what -- what -- what is done by the institution.

Q. You don't know whether Gentamicin is more or less effective than Gentamicin plus Teicoplanin --

A. Well that's a different question.

Q. -- in terms of deep joint infection. That's the question right now. Do you know?

A. Well there is the --

The analysis based on these data --

Q. That shows --

A. -- found -- found the -- the result was not statistically significant, the difference of 2.19 percent versus 3.1, but -- but --

Q. And the infection rate went up with Gentamicin plus Teicoplanin.

A. That's right.

Q. Okay.

A. The one -- the one is higher. It's not --

That difference is not statistically significant.

Q. Okay. Based on that --

A. When I -- when I added that into the analysis and controlled for that after I had already controlled from thromboprophylaxis, the -- any association that -- an association that was 2.1 -- six was it? -- com -- disappeared effectively completely, I mean 1 -- 1. -- 1.11 percent versus 1.08.

Q. Okay. Let's talk about --

A. So they're basically -- I mean it -- as --

It would, I -- I -- I suggest, be an indication that this is a confounding variable because the odds ratio is bas -- basically eliminated.

Q. Have you done a powering analysis of this double-control calculation?

A. A power analysis, no.

Q. You have no idea whether this is adequately powered.

A. Oh, it's -- I -- there's --

There's never been a power analysis of anything related to McGovern.

Q. You don't know whether this calculation --

A. I don't -- I mean why are --

What is the issue? The power to do what? I don't know what you're asking.

Q. You're analyzing a population of 270 persons and 372 persons, totaling approximately 600 people; correct?

A. So what's your -- what's your hypothesis?

Q. My question is: If the McGovern study was, in your words, a relatively small population based on the incidence of infection and was therefore unreliable, --

A. Yeah.

Q. -- you've cut the population in half.

A. Okay.

Q. Doubly unreliable.

A. Well whether it's double or not, I -- it's not -- it's un -- it's unclear.

Q. More unreliable.

A. It -- it will be more -- more -- it will have less --

The study would have -- would have even less power, that's true.

Q. More unreliable.

A. What do you mean by "reliable?"

Q. More variance.

A. More variance, yes.

Q. If anything, the best way to figure out whether the thromboprophylaxis and the antibiotic confounded the results in a population of patients who were subjected to Bair Hugger warming versus Hot Dog warming would be to look at a larger sample size when both of those variables are controlled; correct?

A. Well one would have to look at what the --

What I think is needed is a proper protocol --

Q. Okay.

A. -- which would address the issue of power, and you would have to specify what magnitude of effect you wanted -- wanted to detect, --

Q. Okay.

A. -- and this, as far as I can tell, was never done by this group.

Q. Okay. I'm going to ask the question again because that didn't respond to it.

A better analysis than what you have done here with respect to controlling for both var -- variables would be to look at a larger population of patients who received the same thromboprophylaxis and the same antibiotic; correct?

A. Well --

Q. There would be less variance.

A. Oh, if you -- if you -- if you restricted both of those, but I mean that's not your only option. If you restricted it to those groups and had an increased sample size, that would -- that would certainly give you more power.

Q. Yeah. It would -- it would be a more accurate representation of whether those two variables were confounders or not; correct?

A. If that's what you were interested in.

Q. Okay. It would be a more accurate representation as to whether there in fact is an increased odds ratio; correct?

A. For -- for --

Q. The use of the device and the outcome of infection.

A. The use of the device. It would give a better estimate of that, yes.

Q. Okay. The recent Augustine study does that; correct?

A. The -- this is the published -- the one that was just published?

Q. Yeah.

A. Well, I mean the recent study has its own -- has a -- has the potential for bias that is also in

McGovern.

Q. Okay. But my question is different. The recent Augustine article has a larger patient population; --

A. It's a larger patient population.

Q. -- correct?

A. It is a larger patient population. I think it is, yes.

Q. And the article notes that there was no change in the thromboprophylaxis or the antibiotic regimen; correct?

MR. GORDON: Object to the form of the question, assumes facts -- mis -- it completely misstates the evidence.

A. I -- the -- the --

The paper says very little about -- very -- very little detailed about -- about -- about the population. I think it says that, yes.

Q. Okay. So we've established that it's a larger population and that the study does say that there was not a change in the thromboprophylaxis or antibiotic; is that correct?

MR. GORDON: Counsel, it doesn't -- it doesn't say that. Let him read it if you're going to, you know, make it up, make up stuff.

THE VIDEOGRAPHER: We have 20 -- 21 minutes remaining.
Q. With respect to making causal inferences, mechanistic studies may be helpful; correct?
MR. GORDON: Object to the form of the question.
A. What type of mechanistic studies are you -- are you indicating?
Q. So a study or a document that shows the biological plausibility or the mechanism of infection by which either a drug or a device or --
A. Okay.
Q. -- some entity might result in an increased outcome at issue.
A. That can help, yes.
Q. That can help.
A. Yes.
Q. And in the event of two products, for example, --
A. Uh-huh.
Q. -- would it be helpful if one particular product, albeit a different product, had the same mechanism of infection as a different product?
MR. GORDON: Object to the form of the question.

A. I guess I would have to know exactly what the -- what -- what was -- what -- what you're -- what was involved in the two products and which was --
Q. So in the event that there is one product like the Bair Hugger where Dr. Samet opines that one of the causal mechanisms is the disruption of airflow currents in the operating room that then deposit bacteria on the surgical site, if that's the mechanism of the Bair Hugger for the sake of an example --
Do you understand?
A. Okay.
Q. -- and if there were another product that involved the same mechanism of infection of creating currents of air in an operating room that caused bacteria to be deposited at the surgical site, those are the same mechanisms of infection; correct?
A. Uh-huh.
Q. But they're different products, for example.
A. Okay.
Q. Because the mechanism is the same, would that contribute to coherency of drawing an inference about causation?
MR. GORDON: Object to the form of the question, incomplete hypothetical, assumes facts not in evidence, lack of foundation.

A. Well it -- I mean I think if -- if -- It depends a lot, I think, on what the -- what the outcome is on -- on the -- the study that you're --
Q. Same outcome. Let's say --
A. Infection?
Q. -- infection and that --
A. Deep infection?
Q. -- that's the one you've always been worried about.
A. Okay. So if you're looking at a deep infection, if that is the outcome that you're measuring with these -- with these two different devices, then -- then I think it would be helpful.
Q. What if it was SSI versus DJI?
MR. GORDON: Same objection.
A. It -- there it -- I mean when you start getting away from it, then you really have to get into the details of what it is that -- that you're -- what -- what it is you're looking at and where the -- where the potential differences could be.
Q. You need to look into those details with respect to whether the SSI intervention measures have an impact on deep joint infection; correct?

A. I was not separately studying the -- the SSI and -- and DJI, yeah.
Q. Okay. But with respect to the two devices that share the same exact mechanism of infection that would both increase the risk of infection, that would be helpful in determining whether there was biological plausibility or coherency to whether there was an increased risk of infection; correct?
MR. GORDON: Same objection.
A. It -- it -- it could be.
Q. Okay.
A. I don't know.
Q. Okay.
A. It depends on the details.
(Exhibit 30 was marked for identification.)
BY MR. SACCHET:
Q. This is a document from the CDC; correct, Dr. Holford?
A. It appears to be.
Q. Are you familiar with HICPAC?
A. I'm not familiar with it, no.
Q. Okay. If you could please turn to page 24 of that document, there is a title that says "Nontuberculosis Mycobacterium Infections Associated